

REMARKS

Claims 11, 13, and 15 -10 are currently pending. Claims 1-7, 12 and 14 were previously canceled. Claims 8-10 are canceled in this amendment. New claim 17 is supported by previously presented claims 11 and 13. New claims 18 and 19 are supported by paragraphs [0025] and [0026] of the application as filed.

Claim Rejections --35 USC § 112 (page 2-3 of the office action)

Claim 16 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejected claim 16 stating that the phrase “such as” in claim 16 renders it indefinite. Claim 16 has been amended and the phrase “pains, such as” has been replaced with “the pains of”. Applicants respectfully submit that this rejection has been overcome and claim 16 is definite and distinctly claims the invention.

Claim Rejections under 35 U.S.C. §102 (pages 2-4 of the office action)

The present application discloses and claims an analgesic and anti-inflammatory patch comprising an aqueous poultice material containing 10 to 80 wt% water, 0.5 to 20 wt% of benzocaine, and at least one ingredient having a counter-irritation effect selected from the group consisting of l-menthol, dl-menthol, dl-camphor, d-camphor, methyl salicylate, glycol salicylate, mentha oil, eucalyptus oil, capsaicin, capsicum extract, and nonyllic vanillylamide (see claim 13).

The ingredient having a counter-irritation effect, i.e., counter-irritant, is a medicine applied locally to produce superficial inflammation in order to reduce deeper inflammation; however, the counter-irritant causes unpleasant irritation at the topically applied skin surface.

The patch taught by the applicants reduces pains, such as muscle pain, joint pain, lumbago, shoulder stiffness, fracture pain and other symptoms associated with pain,

without unpleasant irritation when topically applied, while being highly effective. The counter-irritant of the present application shows analgesic and anti-inflammatory effect by producing superficial inflammation in order to reduce deeper inflammation. However, the counter-irritant causes unpleasant irritation, such as pain or stabbing pain. The applicants have found that when benzocaine is also included as an active ingredient, along with an effective amount of a counter-irritant, the result is a reduction in the unpleasant irritation of the counter-irritant, while having a high anti-inflammatory and analgesic effect.

Claims 8-9 were rejected under 35 U.S.C. § 102(b) as being anticipated by Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) as evidenced by Patel et al. (US Patent No. 4855294)

Claims 8 and 9 were both deleted from the claims, so this rejection is no longer relevant. Deletion of these claims does not imply acceptance of the rejection, but it would not be efficient for either the applicants or the Examiner to discuss a rejection that no longer applies to the pending claims.

Claim 15 was rejected under 35 U.S.C. 102(b) as being anticipated by Juni (US Patent No. 6120792).

The Juni patent calls for a medicated skin patch that includes a bibulous pad that imbibes a topical anesthetic. “Bibulous” means “highly absorbent”¹. Suggested materials include “cotton wool, woven textiles, nonwoven textiles, paper pulp and polymeric foams, most preferably hydrophilic polymer” which are “capable of absorbing and holding a liquid or gel.” (Column 2, lines 16-21 of the Juni reference). In contrast, applicants teach and claim an aqueous poultice that would be contrary to highly absorbent. The Juni patent does therefore not anticipate claim 15.

¹ Merriam-Webster's Free Medical Dictionary, www.merriam-webster.com/medical/bibulous, attached as Appendix

Claim Rejections --35 USC Sec. 103 (pages 4-12 of the Office Action)

Claims 10-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) as applied to claims 8-9 above, and further in view of Bernstein (US Patent No. 4997853).

Claims 8-10 were cancelled in this amendment. With regard to claim 11, Bernstein fails to disclose a patch in the form of an aqueous poultice material containing 10 to 80wt% water.

Moreover, Bernstein only discloses capsaicin; there is no mention or suggestion of l-menthol, dl-menthol, dl-camphor, d-camphor, methyl salicylate, glycol salicylate, mentha oil, eucalyptus oil, or and nonylic vanillylamide, nor the suggestion of using up to 5wt% of capsaicin. The largest amount of capsaicin suggested in Bernstein is 1wt% (see claim 5 and column 1, line 42 of the Bernstein reference). In addition, the focus of the Bernstein reference is to use benzocaine to reduce burning and pain caused by use of capsaicin. There is nothing in Bernstein that would suggest the combination of benzocaine and counter-irritant for non-superficial pain, since Bernstein is directed to "superficial pain syndromes such as postherpetic neuralgia" (See column 1, lines 13-14). For the same reasons, claim 11 is not obvious in view of the combination of Yamasaki and Bernstein.

Claims 13 and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) in view of Juni (US Patent No. 6120792).

As discussed above, Juni describes a topical anesthetic imbedded in a bibulous pad. Thus, the topical anesthetic would be absorbed and maintained in the bibulous pad. There is no reason why the two cited references would be combined to produce the patch in the form of an aqueous poultice material containing 10 to 80wt% water and containing both benzocaine and a counter-irritant, as described and claimed in the present invention. There could be no reason other than impermissible hindsight to completely change the form of the Juni patch into an aqueous poultice as claimed and combine it with the Yamasaki reference to obtain the patch and method of the present invention.

Claims 13 and 16 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) in view of Hirashima et al. (US Patent No. 6471984). All of the cited patents are attached

Hirashima et al. relates to a plasticizer for a medicated base for use in a medicated patch. The drugs used in the patch are incidental to description of the plasticizer and its use in Hirashima. The drugs to be used in the patch of Hirashima et al. are not the focus of the disclosure and are presented as a laundry list of anything that could possibly be used. There is no reason, other than hindsight using the present application, to select benzocaine out of this list. As stated in the Hirashima reference:

The drug to be used in the patch of this invention is not particularly limited but may be arbitrarily selected from among known conventional drugs.

(Column 2, lines 47-48). Even more telling, methyl salicylate and glycol salicylate are buried in a list of dozens of additives to the hydrophilic base of Hirashima and identified as ultraviolet absorbers, not as counter-irritants. No one skilled in the art would have any reason to combine these two random components of the Hirashima et al. patent except by using the present application as a guide and impermissible hindsight to conduct a computer search to select these two items out of the hundreds listed in the Hirashima et al. reference. Moreover, Hirashima does not list the other counter-irritants claimed. Likewise, one would not combine the Hirashima and Yamasaki et al. references to obtain the patch and method of the present invention as claimed in claims 13 and 16.

Applicants respectfully submit that the claims as presented are in condition for allowance.

CONCLUSION

If the Examiner has any questions or suggested Examiner's amendments, the Examiner is respectfully requested to call the undersigned.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 50-3195.


Respectfully submitted,

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Appendix


1. Merriam-Webster's Free Medical Dictionary,
www.merriam-webster.com/medical/bibulous



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bibulous

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Main Entry: *bib-u-lous*
Pronunciation: "bib-yə-ləs"
Function: *adjective*
 : highly absorbent <*bibulous* paper>

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